Non-registration of students fron Tajik and Tashkand Medical Colleges

† *388. SHRI D. P. YADAV: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware that the Medical Council of India is not registering around 70 Indian students of January, 1998 batch who have returned from Tajik and Tashkand Medical Colleges after completing their studies;

(b) whether the students of 1997 batch who have completed five and a half years' course from the same colleges alongwith the students of 1998 batch have been registered after an order from the court;

(c) if so, whether MCI is taking any action for registration of students who have completed the course in January, 1998 batch; and

(d) if so, by when and if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR): (a) to (d) As per information received from the Medical Council of India, a large number of students from the Institutions in the erstwhile USSR, including Tajik and Second State Tashkand Institute, who came back to India with medical degrees of 5 Vi years duration were denied registration by the Medical Council of India. This was in the light of a decision taken by the Executive Committee of Medical Council of India on 17/9/1997 and duly approved by the General Body of the Council on 23/10/1997, among others, not to grant registration to the students who have completed their medical degree course in less than six years duration from the institutions in the erstwhile USSR because of the fact that the duration of MD (Physician) course is six years, after one year preparatory/language course.

The Medical Council of India had granted registration to the students of 1995-96 and 1996-97 batches who had come back to India with the medical degree of 5 Vi years duration from the institutions in erstwhile USSR. However, the Council has not granted registration to any such students after the decision taken by the Executive Committee of the Council on 17/9/1997.

Aggrieved by the decision taken by the General Body of the Medical Council of India on 23/10/1997, a number of students approached various

† Original notice of the question was received in Hindi.

High Courts in the country. All such matters have been clubbed together and is at present pending adjudication before the Hon'ble Supreme Court of India for final decision.

Procedure adopted for permission of new drugs

*389. SHRI MUNAVVAR HASAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the procedure being adopted for the permission of new drugs;

(b) the normal time taken for the grant of permission for the new drugs;

(c) the names of the new drugs for which permission has been granted during this year; and

(d) the time taken in each case?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C. P. THAKUR): (a) to (d) The requirement for evaluation of a new drug application for market authorisation are prescribed under rules 122A to E and Schedule 'Y' of the Drugs and Cosmetics Rules, 1945. The modalities *inter-alia* include initial evaluation of chemical and physical characterstics, animal toxicity, pharmacokinetics and pharmacodynamics of the drug. This evaluation is done by the office of the DCG(I) with the help of experts. It also involves approval of protocols for clinical trials as well as scrutiny of data generated by various clinical trials and result of the testing of the new drug by the Central Government Laboratories.

This evaluation of a new drug application is a complex process. The time taken varies according to the nature of the molecule/drug and depending upon the nature of the application. It may normally take more than five years for approval of Investigational New Drug (a drug molecule not tested on human beings anywhere in the world), about 1-3 years for the first time approval in India of a drug already approved elsewhere and about 2-3 months for subsequent applications by other manufacturers for drugs already approved for market authorisation in India. This is, however, subject to timely submission of all required data as per provision of Schedule 'Y' of the Drugs and Cosmetics Rules by the applicant. Certain categories of the drugs, *viz.* anti-cancer, anti-AIDS, etc. are examined on a fast track mode.

A list of New Drugs approved this year (1st Jan. 2001 to 30th June 2001) is annexed as statement.